

various training and development programs to promote high performance of its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing this training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide: (1) First hand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Management Site Tours and Regulatory Interaction Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, accompanied by a senior level regulatory project manager, may observe operations of pharmaceutical manufacturing, packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management team techniques and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection will be based on the availability of funds and resources for each fiscal year.

If your firm is interested in offering a site tour or learning more about this

training opportunity, please respond within 60 days of this notice by submitting a proposed agenda to Patricia A. Stewart (see **FOR FURTHER INFORMATION CONTACT**).

Dated: October 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 21, 2003, from 8 a.m. to 5 p.m.

Location: Gaithersburg Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of <http://www.fda.gov/cdrh/panelmtg.html> for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on two premarket approval applications (PMAs) for injectable devices intended to restore soft tissue facial contours such as nasolabial folds. Background information for each PMA, including the agenda and questions for the committee, will be available to the public 1-business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. The

material for this meeting will be posted on November 20, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 7, 2003. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:30 a.m., 11:30 a.m. and 11:45 a.m., 1:15 p.m. and 1:30 p.m., and 4 p.m. and 4:15 p.m. Time allotted for oral public presentations may be limited. Those desiring to make formal oral presentations should notify the contact person before November 7, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 16, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0478]

Draft Guidance on Marketed Unapproved Drugs; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Marketed Unapproved Drugs; Compliance Policy Guide." This draft guidance describes how FDA intends to exercise its enforcement discretion with